

**CLEAN VERSION OF AMENDMENTS**

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1. (amended) A process for producing an oral dosage form with sustained release of

active ingredient, comprising

- a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone
- b) at least one active ingredient
- c) optionally water-soluble polymers or low or high molecular weight lipophilic additives
- d) and, optionally, other excipients,

wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to from 40°C to 130°C.

2. (amended) A process as claimed in claim 1, wherein the polyvinyl acetate to polyvinylpyrrolidone ratio is 6:4 to 9:1.

3. (amended) A process as claimed in claim 1, wherein the active ingredient : water-soluble polymers or low or high molecular weight lipophilic additives ratio employed in the combination is from 5:95 to 85:15.

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7. (amended) A process as claimed in claim 1, wherein the excipients employed are

fillers, disintegrants and adsorbents, lubricants, flowability agents, dyes, stabilizers, antioxidants, wetting agents, preservatives, release agents, flavorings or sweeteners.

8. (amended) A process as claimed in claim 1, wherein fillers are selected from the group consisting of lactose, cellulose powder, mannitol, calcium diphosphate and

starch are employed as excipients.

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10. (amended) A process as claimed in claim 1, wherein production is possible both continuously or batchwise.

Not a positive limitation

11. (amended) A process as claimed in claim 1, wherein further processing of the granules, principally the forced screening, can take place both in the hot state or in the cooled state.

12. (amended) A process as claimed in claim 1, wherein besides the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, further release-sustaining excipients may optionally be employed before, during or after the granulation.

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14. (amended) A process as claimed in claim 1, wherein the water-soluble polymers employed are alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives are selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose and carboxymethylcellulose; starch derivatives selected from the group consisting of carboxymethylstarch, degraded starch, maltodextrins, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers, polyvinyl alcohols, high molecular weight polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers and high molecular weight polyvinylpyrrolidones.

15. (amended) A process as claimed in claim 1, wherein the lipophilic substances employed are fatty alcohols consisting of stearyl alcohol; fatty acids selected

134 from the group consisting of stearic acid, glycerides, fatty acid esters and fatty alcohol esters; lipophilic polymers selected from the group consisting of ethylcellulose, cellulose acetate, acrylic ester/methacrylic ester copolymers, methacrylic acid/acrylic ester copolymers, cellulose acetate phthalate, cellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, and hydroxypropylmethylcellulose acetate succinate.

16. (amended) A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones, vinyl acetate/vinyl pyrrolidone copolymers, polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers or maltodextrins, and salts thereof.

17. (amended) An oral dosage form comprising

- a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone
- b) at least one active ingredient
- c) optionally water-soluble polymers or low or high molecular weight lipophilic additives
- d) and, optionally, other excipients,

wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to from 40° to 130°C.

135 19. (amended) An oral dosage form as claimed in claim 18, which comprises active pharmaceutical ingredients as active ingredients.

135 20. (amended) An oral dosage form as claimed in claim 18, wherein the active pharmaceutical ingredient is selected from the group consisting of benzodiazepines, antihypertensives, vitamins, cytostatics, anesthetics, neuroleptics, antidepressants, antibiotics, antimycotics, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics, psychopharmaceuticals, antiparkinson agents and other antihyperkinetics, ophthalmologicals, neuropathy products, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulator peptides and their inhibitors, hypnotics, sedatives gynecologicals, antigout agents, fibrinolytics, enzyme products and transport proteins, enzyme inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium channel blockers, ACE inhibitors, arteriosclerosis remedies, antiinflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarrhythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists and weight-reducing agents.

136 24. (amended) The method of using the oral dosage forms as claimed in claim 17 for producing drug products with delayed release of active ingredient.

B6 25. (amended) The method of using the oral dosage forms as claimed in claim 17 for the delayed release of active ingredients in the form of food supplements or additives, vitamins, minerals or trace elements.

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